

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

ERIC L. JEFFRIES,)	CASE NO. C-1-02-351
	:	
Plaintiff,)	JUDGE BECKWITH
	:	
v.)	
	:	
CENTRE LIFE INSURANCE CO., et. al.,)	
	:	
Defendants.)	

PLAINTIFF'S MEMORANDUM OPPOSING DEFENDANT'S
DAUBERT MOTION AND MEMORANDUM REGARDING
HEPATITIS B VACCINATION CAUSATION EXPERT TESTIMONY

SUMMARY OF FACTUAL/LEGAL ANALYSIS

This Court should deny defendant's request to exclude from the trial of this case that portion of the testimony of Drs. Hyde, Geier, and Waisbren (*and other experts whose opinions the defendant does not challenge*) which asserts that the hepatitis B vaccine Mr. Jeffries received just prior to the onset of his illness caused his undisputed disability, which plaintiff's experts establish as chronic fatigue syndrome ("CFS").

In its motion, the defendant disregards: medical science; the vaccine manufacturer's caution concerning its product; the opinions of defendant's own experts; and a federal law acknowledging that the hepatitis B vaccine can causes illness. The defendant also overtly attempts to mislead the Court concerning the credibility of plaintiff's experts. Defendant does so because it has now conceded that Mr. Jeffries' is "Totally Disabled," but to prove its case (a mental disorder) the defendant must keep from the jury the scientifically valid, medically-based explanation for Mr. Jeffries' undisputed disability.

I. Analysis.

Federal Rule of Evidence (“FRE”) 702 and *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993), permit opinion testimony by experts as to matters amounting to “scientific . . . knowledge” which will “assist the trier of fact to understand the evidence or to determine a fact in issue.”

Plaintiff’s experts’ testimony is admissible under *Daubert* because the reasoning and/or methodology underlying their testimony is scientifically valid and is properly applied to the facts in issue: their theories have been subjected to peer review and publication, and there is a substantial degree of acceptance within the scientific community (including within the opinions of defendant’s own doctors). The test of reliability is “flexible.” Here, the test applied under these facts warrants the denial of defendant’s motion.

A. The Scientific Validity Of The Opinions Cannot be Seriously Questioned.

1. Federal Law Recognizes That The Hepatitis B Vaccine May Cause Illness.

Congress has passed into law the National Vaccine Injury Compensation Act. *See*, 42 U.S.C. § 300aa-10, *et. seq.* The Act provides compensation to recipients of the hepatitis B vaccine if the vaccine causes injury.

2. Vaccine Manufacturers Recognize That The Hepatitis B Vaccine Causes Illness.

The information disclosure accompanying the hepatitis b vaccine acknowledges the medical, scientific, and tested reality that inoculation with the hepatitis B vaccine may result in adverse reactions, *including reactions such as some of those suffered by Mr. Jeffries.*

3. Defendant's Experts Concede That Plaintiff's Expert's Testimony Is The Product Of Reliable Principles and Methods Which Have A Degree Of Acceptance In The Medical Community.

- Dr. Robert Curran, advised that "vaccines indisputably trigger autoimmune diseases;"
- Dr. Newton Bullard, defendant's purported medical expert for trial, testified that he has "treated patients that have suffered adverse reactions to vaccines . . . [and] it is well recognized" that the hepatitis B vaccine does trigger adverse reactions. He also testified that Mr. Jeffries' symptoms are not inconsistent with symptoms you may expect to suffer in an adverse reaction to a vaccine;
- Dr. Donald Craven, defendant's "hepatitis B expert," advised defendant that "there is a relationship between the hepatitis b vaccine and rare auto-immune illnesses;" and
- Dr. James Garb, advised defendant that adverse reactions to the hepatitis B vaccine do occur, including reactions triggering symptoms Mr. Jeffries has experienced ("recent literature reveals numerous case reports of immunologic type reactions following administration of the hepatitis B vaccine"). Dr. Garb advised defendant that the evidence is inadequate to reject a causal relation between the hepatitis B vaccine and diseases. Dr. Garb further comments that "people who are HLA-B27 positive, as is Mr. Jeffries, may be more susceptible to this type of reaction."

4. Medical science. It is established that it is biologically plausible that the hepatitis B vaccine caused Mr. Jeffries' injury. There is overwhelming evidence in the medical literature to support this biological plausibility. (See, Exhibits 7-25). The scientific reasoning and methodology underlying the testimony of Drs. Hyde, Geier, and Waisbren is valid and their reasoning and methodology can properly be applied to the facts in issue. And the fact that vaccines can cause myalgic encephalomyelitis (another medical term for CFS) is nothing new. (Exhibit 7). As early as 1988 the medical community recognized that CFS has been associated

with vaccinations as an initiating event, and it further demonstrates that it has long been known that it involves immunological dysfunction.

In addition, Dr. Geier has reviewed the data from the Vaccine Adverse Event Reporting System ("VAERS"), and has published articles in peer-reviewed medical literature that demonstrate that hepatitis B vaccines have been associated with higher levels of reporting of myalgias, arthralgias and the other symptoms that Mr. Jeffries experienced after his vaccination.

All of the symptoms that Mr. Jeffries experienced after hepatitis B vaccination have been reported in the medical literature to be potential sequela of the vaccine.

B. The Expert's Opinions.

The medical plausibility that the hepatitis b vaccine may cause injury cannot be disputed. Here, there is overwhelming proof of causation, but certainly sufficient scientifically valid basis for the opinions of Drs. Hyde, Waisbren, and Geier. And under *Kumho*, "the relevant reliability concerns may focus upon personal knowledge or experience." *Id. at 150.*

1. **Dr. Mark R. Geier.** Dr. Geier's research and experience is published in numerous medical journals. *Id.* His publications include many reports (approx. 30) concerning adverse reactions to several different vaccines, and a large amount of Dr. Geier's research and published reports concern the hepatitis B vaccine, specifically.

On the basis of his work, knowledge, and review of Mr. Jeffries' medical records, it is Dr. Geier's opinion that Mr. Jeffries' illness and disability were caused by the hepatitis B shot that he received. Without reliance upon any sworn testimony or even a citation to a specific person, the defendant argues that Dr. Geier's reasoning has been criticized. However, Dr. Geier's reply to the anonymous, unpublished criticism of his work did appear in a peer-reviewed medical

journal. Moreover, defendant's argument that unanimity of opinion among scientists is the talisman of *Daubert* is meritless. In *Daubert* the Supreme Court held that: "of course it would be unreasonable to conclude that the subject of scientific testimony must be 'known' to a certainty . . . and a rigid 'general acceptance' requirement would be at odds with the 'liberal thrust' of the Federal Rules."

2. Drs. Hyde, Waisbren, Poser, and McClellan, These experts (2 are challenged, 2 are not), based on their personal examination of Mr. Jeffries, sound scientific principles, experience, and observations, opine that the hepatitis B vaccine administered to Mr. Jeffries just prior to the onset of his illness caused him to suffer an autoimmune illness and chronic fatigue syndrome. Without reference to, or reliance upon, any person's testimony or any identifiable information, defendant challenges this testimony. However, as detailed herein and in the attached exhibits, these opinions are soundly based on valid scientific principles.

Conclusion

The reasoning and methodology underlying the testimony of Drs. Hyde, Geier, and Waisbren is scientifically valid and is properly applied to the facts in issue. Their testimony will "assist the trier of fact to understand the evidence or to determine a fact in issue," namely the cause of Mr. Jeffries' undisputed disability. For the above reasons, the Court should deny defendant's prayer and allow Drs. Hyde, Waisbren, and Geier to offer their opinions at trial.

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**PLAINTIFF'S MEMORANDUM OPPOSING DEFENDANT'S
DAUBERT MOTION AND MEMORANDUM REGARDING
HEPATITIS B VACCINATION CAUSATION EXPERT TESTIMONY**

Plaintiff's experts and treating physicians, Drs. Hyde, Geier, and Waisbren (*and other experts whose opinions the defendant does not challenge*) have concluded that the hepatitis B vaccination that Mr. Jeffries received just prior to the onset of his illness has caused Mr. Jeffries' undisputed disability. This Court should deny defendant's request to exclude from the trial of this case that portion of the testimony of these experts which asserts that the hepatitis B vaccine caused Mr. Jeffries' to develop chronic fatigue syndrome.

In its motion, the defendant turns back time on medical science, disregards the vaccine manufacturer's caution concerning its product, disregards the opinions of *its own* experts, and nullifies a federal law acknowledging that the hepatitis B vaccine can causes illness.

I. Background.

In June 1997, Mr. Jeffries received a hepatitis B vaccination, during a period of time when he otherwise had an acute illness. He developed a lump at the site of his shot, which was later surgically removed.

Immediately after receiving the vaccination, Mr. Jeffries complained to his physician of failing health, including, *inter alia*, severe muscle pain, joint pain, cognitive difficulties, and fatigue. Mr. Jeffries' treating physician contacted the vaccine manufacturer who advised that Mr. Jeffries was suffering from an allergic reaction to the vaccine.

Over the next several months, Mr. Jeffries' illness progressively worsened. As defendant's experts concede, based on their own testing of Mr. Jeffries, his cognitive functioning

has substantially deteriorated. And in 1998, Mr. Jeffries' illness prevented him from continuing in his occupation.

Although defendant now concedes that Mr. Jeffries is and remains "Totally Disabled" within the meaning of the Policy, defendant argues that it is only obligated to pay 24-months of benefits to Mr. Jeffries. (*See, Answer and Counterclaim, Doc. 89*). Defendant bases its argument on its contention that Mr. Jeffries suffers from a mental disorder, not a medical illness, and an Amendment to the Policy contains the following limitation:

"Amendment To Policy. Mental Disorder and/or Substance Use Disorder Limitation: If a Total Disability . . . is due to a Mental Disorder . . . the number of months for which any benefits for Total Disability shall be payable under the Policy during the lifetime of the Insured shall not exceed in the aggregate a total of 24 months. 'Mental Disorder' . . . means a manifestation of any disorder classified in the then current issue of the Diagnostic and Statistical Manual of Mental Disorders (DSM) published by the American Psychiatric Association (APA)." (*See, Policy, p. 12*).

In the only written expert reports provided to plaintiff, defendant's psychologist experts (Drs. Clionsky and Hartings) contend that Mr. Jeffries suffers from "Somatization Disorder." In his deposition which followed the preparation of his report, however, Dr. Hartings modified his diagnosis. Dr. Hartings no longer argues that Mr. Jeffries has "Somatization Disorder," rather, he now argues that Mr. Jeffries has a completely different diagnosis, "Undifferentiated Somatoform Disorder." Dr. Hartings, however, may not properly make this diagnosis unless there exists no medical explanation for Mr. Jeffries' symptoms.

Accordingly, to have any hope of meeting its burden of proof, the defendant necessarily must first keep from the jury's appreciation of the case the evidence that Mr. Jeffries' symptoms are caused by a medical illness likely triggered by the hepatitis B vaccine he received.

II. Defendant's Overt Attempt To Mislead The Court.

In its motion, defendant overtly attempts to falsely mislead the Court into summarily concluding that plaintiff's expert opinions on the hepatitis B vaccination causation issue are unreliable.

Specifically, defendant misrepresents the outcome of a claim for benefits brought by Mr. Jeffries in the Court Of Federal Claims under the National Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-10, *et. seq.* (the "Act"). In that action, Drs. Hyde and Geier (2 targets of defendant's present motion) were permitted to testify at trial, notwithstanding a *Daubert* challenge made by the Department Of Justice attorneys representing the Health and Human Services Department.¹ In its motion, the defendant falsely asserts (as it now was forced to admit) that Mr. Jeffries' claim for benefits under the Act "was denied." (*Doc. 117, p. 6*). Defendant's assertion is false, and is the subject of a separate motion for sanctions. (*Doc. 125*).

Defendant knowingly made this misrepresentation in a calculated effort to falsely discredit Mr. Jeffries' experts.

III. Framework Of Legal Analysis.

Applying FRE 702 and *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993), this Court should deny defendant's motion. FRE 702 permits opinion testimony by experts as to matters amounting to "scientific . . . knowledge" which will "assist the trier of fact to understand the evidence or to determine a fact in issue." Here, as required by FRE 702:

¹ Upon hearing the expert testimony of Drs. Hyde, Geier, and others, the Special Master overseeing Mr. Jeffries' Claim ordered the parties to engage in an arbitration to determine damages.

- (i) Drs. Geier, Hyde, and Waisbren are all qualified as experts by their knowledge, skill, experience, training, and/or education;
- (ii) The opinions of Drs. Geier, Hyde, and Waisbren are based upon sufficient facts or data;
- (iii) The testimony of Drs. Geier, Hyde, and Waisbren is the product of reliable principles and methods; and
- (iv) Drs. Geier, Hyde, and Waisbren have applied the principles and methods reliably to the facts of this case.

The Supreme Court in *Daubert* stated that “of course it would be unreasonable to conclude that the subject of scientific testimony must be ‘known’ to a certainty.” *Id.*, at 590. In order “to qualify as ‘scientific knowledge’ an inference or assertion must be derived by the scientific method [and] proposed testimony must be supported by appropriate validation - i.e., ‘good grounds,’ based on what is known.” *Id.*² “Nothing in the text of this Rule establishes ‘general acceptance’ as an absolute prerequisite to admissibility . . . and a rigid ‘general acceptance’ requirement would be at odds with the ‘liberal thrust’ of the Federal Rules.” *Id.*, at 588.

Accordingly, the Supreme Court concluded that the “austere [general acceptance] standard, [which is] absent from, and incompatible with, the Federal Rules of Evidence, should not be applied in federal trials.” *Id.* at 589.

After abolishing *Frye*, the Supreme Court noted that the trial court must preliminarily assess “whether the reasoning or methodology underlying the testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue.”

² The principle thrust of *Daubert* was to abolish the earlier established *Frye v. Untied States* 293 F. 1013 (D.C. 1923) rule, which held that “the thing from which [an expert’s deduction] is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs.” *Daubert* 509 U.S. at 586-587.

Id. at 592-593. The Supreme Court left it to federal judges “to undertake this review . . . we do not presume to set out a definitive checklist or test.” *Id.*

Having established this framework, the Supreme Court noted that the following considerations would ordinarily be pertinent “in determining whether a theory or technique is scientific knowledge that will assist the trier of fact:”

- Whether it can be tested;
- Whether the theory or technique has been subjected to peer review and publication. (However, “in some instances well-grounded but innovative theories will not have been published . . . [accordingly] the fact of publication (or lack thereof) in a peer reviewed journal will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised”) *Id.* at 593;
- In “the case of a particular scientific technique, the court ordinarily should consider the known or potential rate of error;”
- The degree of acceptance within the scientific community. (Although the Supreme Court abolished the “general acceptance” standard developed in the earlier *Frye* case, the Court stated that the degree of acceptance can “have a bearing;” a “reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community”) *Id.* at 594.

In conclusion the Supreme Court stated that “the inquiry envisioned by Rule 702 is, we emphasize, a flexible one.” *Id.* at 594.³ The “scientific validity . . . of the principles that underlie a proposed submission” is the focus. *Id.* at 595. Experts pass *Daubert* muster based “solely on principles and methodology, not on the conclusions that they generate.” *Id.*

³ In *Kumho*, the Supreme Court clarified that whether the factors set forth in *Daubert* are reasonable measures of reliability in a particular case “is a matter that the law grants the trial judge broad latitude to determine . . . [the trial judge has] considerable leeway in deciding . . . how to go about determining whether particular expert testimony is reliable.” *Id.* at 141, 152.

Here the scientific reasoning and methodology underlying the expert opinions of Drs. Hyde, Waisbren, and Geier are scientifically valid and have properly been applied to the facts in issue. Accordingly, defendant's motion should be denied.

IV. Analysis.

In *Kumho v. Carmichael* 526 U.S. 137, 141, the Supreme Court stated "some or all of [the 4 factors mentioned in *Daubert*] might prove helpful in determining the reliability of a particular scientific 'theory or technique . . . [and] a trial court *may* consider one or more of the more specific factors that *Daubert* mentioned when doing so will help determine the testimony's reliability. But, as the Court stated in *Daubert*, the test of reliability is 'flexible,' and *Daubert's* list of specific factors neither necessarily nor exclusively applies to all experts in every case." The law grants a district court "the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination." *Id.* (*emphasis in original*). Here, factors not expressly set forth in *Daubert* warrant consideration at the outset.

A. Federal Law Recognizes That The Hepatitis B Vaccine May Cause Illness.

As stated above, Congress has passed into law the National Vaccine Injury Compensation Act. *See*, 42 U.S.C. § 300aa-10, *et. seq.* The Act provides compensation to recipients of some, not all, vaccines if the vaccine causes injury. The Act does expressly provide compensation to those who suffer an illness as the result of the receipt of the hepatitis B vaccine.

Obviously the Act, and the government fund from which judgments are paid pursuant to the Act, would not exist if there were no medical plausibility to the scientific theory that vaccines cause illness and injury. And as the Supreme Court stated in *Daubert*, "theories that

are so firmly established as to have attained the status of scientific law . . . properly are subject to judicial notice under Federal Rule of Evidence 201." *Id.* at 592, *fn.* 11.

Based on this indisputable fact alone, at least one of the *Daubert's* suggested considerations for the trial court (the "degree of acceptance in the medical community") is likely satisfied. And the fundamental "reasoning and methodology" employed by Drs. Geier, Hyde, and Waisbren (i.e., that vaccines can trigger illness) and which underlies their opinions is valid and can properly be applied to the facts of this case.

**B. Hepatitis B Vaccine Manufacturers Recognize The Probability
That The Hepatitis B Vaccine Causes Illness And Disability.**

The information disclosure accompanying the hepatitis b vaccine acknowledges the medical, scientific, and tested reality that inoculation with the hepatitis B vaccine may result in adverse reactions, including reactions such as some of those suffered by Mr. Jeffries: pain, weakness, arthralgias, myalgias, etc. (See, Exhibit 1). The vaccine manufacturer further acknowledges that "it is possible that expanded commercial use of the vaccine could reveal rare adverse reactions."

On the basis of these vaccine manufacturer acknowledgements, plaintiff's experts' opinions are "the product of reliable principles and methods" as required by FRE 702.

**C. Plaintiff's Expert's Testimony Is The Product Of Reliable Principles
and Methods Which Have A Degree Of Acceptance In The Medical
Community Since Defendant's Experts Concede That Vaccines Cause Illness.**

Defendant's principal argument is that: "the opinions of Mr. Jeffries' experts are not supported by sound medical science." This argument is incorrect as shown by the testimony and opinions of defendant's own experts.

1. Dr. Curran.

Defendant's claim file contains the expert report of Dr. Robert Curran, a medical doctor employed by one of Mr. Jeffries' disability insurers to perform a records IME. (*See, Exhibit 2*).

Dr. Curran advised that it was his opinion that Mr. Jeffries "was in . . . good health until some time after he had received an injection of hepatitis B vaccine . . . [and] vaccines indisputably trigger autoimmune diseases." *Id.*

2. Dr. Newton Bullard.

Dr. Newton Bullard, defendant's purported medical expert for trial, testified that he has personally "treated patients that have suffered adverse reactions to vaccines." (*Exhibit 3, p. 60*). And Dr. Ballard concedes that "it is well recognized" that the hepatitis vaccine does trigger adverse reactions. *Id. at 60-61 (emphasis supplied)*. Dr. Bullard further conceded that Mr. Jeffries' symptoms are not inconsistent with symptoms you may expect to suffer in an adverse reaction to a vaccine. *Id.*

And it is wholly inconsistent for the defendant to argue (*as it does in Doc. 127*) that its medical doctor, Dr. Bullard (who concedes that: (i) "it is well recognized" that the hepatitis vaccine does trigger adverse reactions; and (ii) Mr. Jeffries' symptoms are consistent with someone suffering an adverse reaction) may testify that there is no medical basis for Mr. Jeffries' illness but plaintiff's experts who have done substantial study in this are cannot provide the jury with a contrary opinion based on valid medical science (and on principles that Dr. Bullard concedes exist).

3. Dr. Donald Craven.

During the administration of Mr. Jeffries' claim, the defendant retained a "hepatitis B expert" to assess and opine on the medical plausibility that Mr. Jeffries' illness was caused by his hepatitis B vaccination. (*See, Exhibit 4, Champagne Depo., p. 96; Exhibit 5, Palmer Depo., p. 63; and Exhibit 6, Dr. Garb Report*). That expert, Dr. Donald Craven, "an infectious disease specialist and immunologist in Boston who has lectured about the hepatitis B vaccine" (*Exh. 6*), advised defendant that "there is a relationship between the hepatitis b vaccine and rare auto-immune illnesses." [Mr. Jeffries' experts opine that he has suffered an auto-immune illness in response to the hepatitis B vaccination].

4. Dr. Garb

The defendant also sought the expert counsel and opinion of Dr. Garb. (*Exhibit 6*). In his report, Dr. Garb states that "according to information supplied by the manufacturer based on clinical trials involving over 13,000 doses, [adverse reactions do] occur" (*Id.*, p. 5-6). As noted above, these adverse reactions include the principle symptoms associated with Mr. Jeffries' illness: swelling at the injection site, pain, weakness, abdominal pain, arthralgia, myalgia, and rash. *Id.* Dr. Garb further advised defendant that "the more recent medical literature [reveals] numerous case reports of immunologic type reactions following administration of the hepatitis B vaccine . . . including . . . [neurologic problems such as] CNS demyelination, acute cerebellar ataxia and ophthalmologic complications." *Id.*

Dr. Garb concluded, consistent with the conclusion of the Vaccine Safety Committee of the Institute of Medicine, that the evidence is inadequate to reject a causal relation between hepatitis B and several specific diseases. *Id.* Dr. Garb further comments that "people who are

HLA-B27 positive, as is Mr. Jeffries, may be more susceptible to this type of reaction.” *Id.* (*emphasis added*).

Dr. Garb sought the expert counsel from Dr. Craven mentioned above. According to Dr. Garb, Dr. Craven believes that there may be a relationship between the hepatitis B vaccine and rare autoimmune illnesses and some patients may have underlying disease processes that may accelerated by the vaccine. *Id.*

Dr. Garb concludes that “the record in this case neither proves nor disproves a causal relationship between Mr. Jeffries . . . symptoms and the . . . vaccines he received.” *Id.* Dr. Garb’s report contains a “References” list (*p. 8*), which identifies a number of articles discussing adverse reactions to the hepatitis B vaccine, including “perspectives on hepatitis B vaccinations,” authored by one of plaintiff’s experts, Dr. Waisbren.

5. Summary.

The principal considerations suggested by *Daubert* (whether an expert’s opinions are: (i) based on sufficient data; (ii) the product of reliable principles and methods; and (iii) accepted in the medical community) as they relate to the opinions of Drs. Hyde, Waisbren and Geier are all satisfied based on the concessions of defendant’s experts, the acknowledgements of the vaccine manufacturer, and the authority of Federal law. Defendant should, accordingly, be estopped from arguing that there is no scientific basis for the proposition that the hepatitis B vaccine may have caused Mr. Jeffries’ illness and disability.

**D. Medical Science Recognizes The Probability That The
Hepatitis B Vaccine Causes Illness And Disability.**

It is established that it is biologically plausible that the hepatitis B vaccine caused Mr. Jeffries' injury. There is overwhelming evidence in the medical literature to support this biological plausibility. The scientific reasoning and methodology underlying the testimony of Drs. Hyde, Geier, and Waisbren is valid and their reasoning and methodology can properly be applied to the facts in issue.

In this case, there are both subjective and objective findings of illness. As is conceded, Mr. Jeffries suffers from a substantially diminished cognitive state. Since June 1997, he has experienced recurring and episodically severe episodes of arthralgias, myalgias, nausea, ataxia, vasculitis, as well as all the other symptoms of chronic fatigue syndrome.

The fact that vaccines can cause myalgic encephalomyelitis (another medical term for chronic fatigue syndrome) is nothing new. The article by Lloyd, et al, "What is Myalgic Encephalomyelitis?" *The Lancet* June 4, 1998 (*Exhibit 7*) shows that as early as 1988 the medical community recognized that CFS has been associated with vaccinations as an initiating event, and it further demonstrates that it has long been known that it involves immunological dysfunction.

It is well-recognized in the medical literature that Hepatitis B vaccination contains (1) hepatitis B surface antigen; (2) thimerosal, a mercury-containing preservative; (3) aluminum hydroxide, an adjuvant; and (4) yeast. All of these components are capable of inducing adverse events in individuals who are susceptible. All of these components have been specifically associated with the exact symptoms manifested by Mr. Jeffries after his vaccination.

One of Mr. Jeffries symptoms was diffuse myalgias. Numerous articles have demonstrated that hepatitis b vaccine can cause such myalgias. Each 1mL dose of adult hepatitis B vaccine contains the hepatitis B surface antigen absorbed onto 0.5 mg of aluminum hydroxide adjuvant.

A study by Gherardi, et al. (*Exhibit 8*) designed to identify both local and systemic immunological abnormalities in patients with Macrophagic Myofasciitis (MMF) describes that MMF is characterized by stereotyped accumulation of aluminum hydroxide-loaded macrophages, persisting for years at sites of intramuscular injections of vaccines containing aluminum-based adjuvants. The Gherardi study reports that patients with MMF who demonstrate these findings usually have arthromyalgias and fatigue. They concluded that both local and systemic signs of protracted immune stimulation are constantly associated with MMF and could account for both systemic symptoms of affected patients and concurrent autoimmune disorders.

And Authier, et al. (*Exhibit 9*) report that MMG is a condition manifested by diffuse myalgias characterized by highly specific myoathological alterations which have recently been shown to represent an unusually persistent local reaction to intramuscular injection of aluminum-containing vaccines. Among 92 patients determined to have MMF in their study, 8 of them reported symptomatic demyelinating CNS disorders (like Mr. Jeffries). The authors note that previous studies have implicated aluminum-adjuvants in vaccines as deleterious, and they show that these adjuvants work by depot formation at the site of the injection, and they also induce immune activation that includes IL-1 production by monocytes, eosinophilia, complement activation, and increased specific and non-specific IgG and IgE antibody

responses. Their study suggests that MMF can be associated with autoimmune disease, including systemic lupus erythematosus, rheumatoid arthritis and Hashimoto's thyroiditis. In other words, the arthralgias and myalgias that Mr. Jeffries experienced have a logical basis in science.

In another article by Gherardi, et al. (*Exhibit 10*), they assessed 40 consecutive cases and did chemical analysis by microanalysis and atomic absorption spectrometry. Myalgia onset was subsequent to vaccines in 94% of patients. They were also able to produce MMF lesions in rats by injecting them with aluminum hydroxide-containing vaccines. They showed both long-term persistence of aluminum hydroxide and ongoing local immune reaction, something that was experienced by Mr. Jeffries.

In another article by Authier, et al. (*Exhibit 11*), the authors reviewed 30 consecutive patients with biopsy proven MMF. Chronic fatigue was found in 28 out of 30 patients and was considered to be disabling in 26 out of 30. Sixteen patients fulfilled the Chronic Fatigue Syndrome criteria from the CDC. Other symptoms included muscle pain, joint pain, sleep disturbance, mood disturbance, subjective memory impairment, headache, as well as other symptoms, all of which Mr. Jeffries experienced.

In addition, as discussed in detail below, Dr. Geier has reviewed the data from the Vaccine Adverse Event Reporting System ("VAERS"), and has published articles in the peer-reviewed medical literature that demonstrate that hepatitis B vaccines have been associated with higher levels of reporting of myalgias, arthralgias and the other symptoms that Mr. Jeffries experienced after his vaccination.

It is important to note that all of the symptoms that Mr. Jeffries experienced after hepatitis B vaccination have been reported in the medical literature to be potential sequela of the vaccine. These include: joint pains (arthralgias); muscle pains (myalgias); debilitating fatigue; skin rash; conjunctivitis; tingling limbs; speech disorder or clumsy speech; parasthesias; sweats; heavy legs; electric jolts; and headaches.

The Institute of Medicine (IOM) of the United States' National Academy of Sciences has long considered "positive rechallenge" following immunization as important and strong evidence regarding the ability of a vaccine to cause a specific adverse event following immunization. What this means is that if an individual responds to a vaccination with certain signs and symptoms and then has the same or more severe such reactions to another vaccination with the same type of vaccine, this is strong proof of a causal relationship. The IOM has in fact stated that rechallenge is proof of causation. (*See, Christopher P. Howson et al., Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines*, 48, 53 (1991)(Exhibit 12)). The IOM has also stated that where causation is proven, biological plausibility is a given. (*See, Kathleen R. Stratton et al., Institute of Medicine, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*, 21 (1994)(Exhibit 13)).

In an article by Hassan & Oldman, "Reiter's Syndrome and reactive arthritis in health care workers after vaccination," published in the *British Medical Journal* 1994: 309;94-5 there is evidence of positive rechallenge for developing joint symptoms after hepatitis b vaccination – this correlates to the arthralgias symptom Mr. Jeffries experiences. (Exhibit 14)

Another example of positive rechallenge is provided by the case-series study of Maillefort et al. (Exhibit 15). They describe six women who developed inflammatory

polyarthritis after hepatitis b vaccination. All received another injection. The symptoms worsened in four cases, were not modified in one, and the results in the last one are unknown. On the basis of only one positive rechallenge case (GBS after tetanus vaccine), the IOM concluded that tetanus vaccine can cause GBS. Here we have four such cases in one article.

This is overwhelming proof of causation, but certainly sufficient scientifically valid basis for the opinions of Drs. Hyde, Waisbren, and Geier.

Dr. Geier has found documented cases of positive rechallenge in the VAERS data involving arthritis, arthralgias, arthrosis, myalgia, gait abnormalities, neuropathy, fatigue, chronic fatigue, personality disorders, tremor and neuritis. This is evidence that is published by the CDC.

The Institute Of Medicine has conceded that all of the vaccine-adverse events studied in their 1994 report were theoretically biologically plausible ("a knowledgeable person could postulate a feasible mechanism by which the vaccine could cause the adverse event"), only a few had *demonstrated* biologic plausibility which meant the finding was "based on the known effects of the natural disease against which the vaccine is given and the results of animal experiments and in vitro studies. (*Exhibit 16*, IOM 1994 Report at 5, 28). The IOM only considered *demonstrated*, not *theoretical*, biological plausibility when making the causality judgments. *Id.* at 28. The IOM found that there is biologic plausibility for a causal relationship between vaccines and demyelinating disorders.

It is the overwhelming conclusion that the association between the hepatitis B vaccine and illnesses such as Mr. Jeffries', has been reported many times in the peer-reviewed medical literature.

V. Analysis Of The Opinions Of Plaintiff's Challenged Experts.

As discussed above, the medical plausibility that the hepatitis b vaccine may cause injury cannot be disputed. In essence, the purpose of a vaccine is to stimulate a recipient's immune system to simulate the reaction that his/her immune system would have to the organism for which the vaccine is designed. The vaccine introduces the body to the protein contained in the virus (in this case hepatitis B) so that the body, and specifically the immune system, can later recognize the real virus and produce the agents necessary to destroy the virus. Because not every person's immune system, previous exposure history, and genetic makeup is the same, one person's immune system may overreact to the vaccine, causing the body to attack itself. In addition, vaccines contain a variety of antigens that can also effect the immune system, causing overstimulation and an autoimmune illness.

As Dr. Geier explains, the hepatitis B vaccine contains yeast, aluminum (adjuvant), and thimerosal (a mercury-containing preservative), all of which have a propensity to cause problems. These elements are present in the hepatitis vaccine to a degree which is above what the EPA allows you to have for mercury. Accordingly it can cause neurological damage and problems with the immune system.

It is acknowledged by federal law (which compensates sufferers, 42 USC @ 300aa-10, *et. seq.*) that vaccines can cause this overstimulation and adverse reactions. And defendant's experts' concede the potential that persons can suffer adverse reactions.

As the Supreme Court emphasized in *Kumho*, "engineering testimony rests upon scientific foundations, the reliability of which will be at issue in some cases. In other cases, the relevant reliability concerns may focus upon personal knowledge or experience." (*Kumho* at

150). In this instance the assessment of the reliability of the expert testimony of Drs. Hyde, Geier, and Waisbren focuses as much on the scientific foundation therefor as these experts' personal knowledge and experience.

As stated in *Kumho*, the objective of *Daubert's* gatekeeping function "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho* at 152. These thresholds are easily satisfied here.

A. Dr. Mark R. Geier.⁴

Dr. Mark R. Geier received a Ph. D. in genetics from George Washington University in 1973 and an M. D. from George Washington University in 1978. (*See*, CV of Dr. Mark Geier, Exhibit 17, and Report Exh. 18, filed manually due to its size). He is certified by the American Board of Medical Genetics, a Board Certified Forensic Examiner, and a Board Certified Medical Examiner. *Id.*

Dr. Geier's professional experience is substantial including positions as the Director of Genetics at the Maryland Medical Laboratory and a position as assistant professor at the Johns Hopkins School of Medicine. *Id.* For a significant period of time (15+ years), Dr. Geier has been: (i) the Co-Director of Genetics Consultants; (ii) the Director of the Institute of ImmunoOncology and Genetics; (iii) the President of Genetic Counseling and Research, Inc.; (iv) Laboratory

⁴ Dr. Geier, like Dr. Hyde and others, testified as an expert on behalf of Mr. Jeffries at the trial conducted in the Court of Federal Claims under the ACT, notwithstanding a *Daubert* challenge raised by trial counsel from the Department of Justice. In fact, Dr. Geier has testified approximately 100 times in the United States Court Of Federal Claims, which, in every case before it, assesses the potential that vaccines cause illness and which also employs the *Daubert* gatekeeping function. (*Exh.* 17).

Director of Molecular Medicine; and (v) for seven years has been the President of the Genetic Centers Of America. *Id.*

Dr. Geier's research and experience is published in numerous medical journals. *Id.* His publications include many reports (approx. 30) concerning adverse reactions to several different vaccines dating to 1978 including the DPT, Pertussis, Influenza, MMR, Tetanus, Rubella, Smallpox, Polio, Lyme, Anthrax, and Rotavirus vaccines. *Id.* And a large amount of Dr. Geier's research and published reports concern the hepatitis B vaccine, specifically, including:

- "Hepatitis B Vaccine and Arthritic Reactions: An Analysis of the Vaccine Adverse Events Reporting System, (VAERS), From 1990 through 1997" published in Clinical and Experimental Rheumatology, Volume 18: 789-790, (2000);
- "Hepatitis B Vaccine and Gastroenterological Adverse Reactions" published in Hepato-Gastroenterology Vol. 48 (37), (2001);
- "Immunological Reactions and Hepatitis B Vaccine" published in the Annals Of Internal Medicine" Vol. 134:1155 (2001);
- "Hepatitis B Vaccination Safety" published in the Annals of Pharmacotherapy Vol. 36: 370-374 (2002);
- "Hepatitis B Vaccination and Arthritic Adverse Reactions: A Follow-up Analysis of the Vaccine Adverse Events Reporting System (VAERS) Database" published in Clinical and Experimental Rheumatology Vol. 20:119 (2002);
- Epidemiology of the Vaccine Adverse Events Reporting System (VAERS): Proof Of Causation In Various Cases" published in Mealey Publications & Conference Group, Vaccine Litigation Conference: 407-417, (2002);
- "Clinical Implications of Endotoxin Concentrations in Vaccines" published in the Annals of Pharmacotherapy Vol 36: 776-780 (2002);
- "Cutaneous Immunological Reactions to Hepatitis B Virus Vaccine" published in the Annals of Internal Medicine Vol. 136:780-781 (2002);

- "Hepatitis B Vaccination and Adult Associated Gastrointestinal Reactions: A Follow Up Analysis" published in Hepato-Gastroenterology Vol. 49: 1571-1575 (2002);
- "An analysis of the Reactivity of Vaccines Administered in Texas From 1991 Through 1999: Based Upon the Vaccine Adverse Events reporting System (VAERS) Database" published in Texas Medicine Vol. 57:249-284 (2002);
- "The VAERS and CDC Reportable Disease Databases are New Tools for those in Vaccine Related Forensic Medicine. A Case in Point: Adult Hepatitis B Vaccine," published in The Forensic Examiner Volume 11 (7-8): 21-28 (2002);
- "Vaccine Causation of Selected Adverse Reactions: Epidemiology of the Vaccine Adverse Event Reporting System (VAERS)" published in Thimerosal & Vaccines Volume 1(1):32-42 (2002);
- "Reply: Hepatitis B Vaccination Safety" published in Annals of Pharmacotherapy Volume 36: 1649-1650 (2002);
- "Chronic Reactions Associated With Hepatitis B Vaccination" published in the Annals of Pharmacotherapy 36:1970-1 (2002);
- "A One Year Followup Of Chronic Arthritis Following Adult Rubella and Hepatitis B Vaccination: Based Upon Analysis of the Vaccine Adverse Events Reporting System (VAERS) Database" published in Clinical and Experimental Rheumatology 20:767-71 (2002); and
- "A review of hepatitis B vaccination." Expert Opinion on Drug Safety 2:113-22 (2003). *Id.*⁵

There likely is no one more familiar or more experienced in the research and study of adverse reactions to vaccines, and the hepatitis B vaccine specifically, than Dr. Geier. He has analyzed the VAERS Database in great detail and has performed epidemiology to show that

⁵ These published articles appear in peer-reviewed journals. The reviewers have determined that Dr. Geier's methodology is scientifically valid and his studies regarding adverse reactions to vaccines are scientifically valid. Defendant's argument that Dr. Geier's opinion is not supported by sound, scientific method is meritless.

hepatitis B vaccine is associated with a statistically significant increased relative risk of the very symptoms that Mr. Jeffries has experienced: arthralgias, arthritis, joint disease, neuropathy, myelitis, neuritis, myalgias, vasculitis, and liver abnormalities, among others. *Id. at pp. 20-24.*⁶

The VAERS Database is the most valuable source of information for vaccine forensic examiners. *Id., p. 19.* It has been maintained by the Centers For Disease Control and Prevention (the "CDC") since 1990. By law, all adverse reactions to vaccines must be reported to VAERS. [See, pages 19-20 of Exhibit 18 for a detailed description of VAERS and CDC's tracking of adverse reactions.] According to Dr. Geier, people with a genetic predisposition to autoimmune illness (such as Mr. Jeffries) have a greater chance of experiencing an adverse reaction to the hepatitis B vaccine.

On the basis of his work with the VAERS Database, his knowledge of the scientific validity concerning adverse reactions to vaccines, his review of Mr. Jeffries' medical records, the onset of Mr. Jeffries' illness, and his review of the medical literature, it is Dr. Geier's opinion to a reasonable degree of medical and scientific probability, that Mr. Jeffries' illness and disability was caused by the hepatitis B shot that he received. *Id.* Dr. Geier testified that Mr. Jeffries' case "fits very nicely into the tables in the studies that he has done. The time onset is right where we see it, and others have seen it, and the symptomatology is right where we've seen it . . . therefore, [Dr. Geier believes] it is more likely than not, [Mr. Jeffries' illness] is due to the vaccine." *Id.*

⁶ Defendant incorrectly argues in its motion that there is no evidence of any "scientific fit between [the opinions offered by Drs. Geier, Hyde, and Waisbren] and Mr. Jeffries' factual symptoms." As indicated in Dr. Geier's peer-reviewed work, this is not true: the principal symptoms from which Mr. Jeffries suffers are known to result from the hepatitis B vaccine, even the drug manufacturer's caution lists Mr. Jeffries' symptoms as potential adverse reactions.

The nature of Dr. Geier's opinion is that relying on the statistical analysis he has performed, there is a statistical probability that the hepatitis B shot is the cause of Mr. Jeffries illness. And the scientific methodology employed by Dr. Geier has been accepted by numerous peer reviewers and numerous medical journals, and by the CDC itself, which approved of Dr. Geier's analysis.

Without reliance upon any sworn testimony or even a citation to a specific person, expert or otherwise, or study, the defendant argues that Dr. Geier's opinion is not reliable because he relies on his statistical research of the VAERS database. In support of its argument, defendant points to anonymous, unpublished criticism of Dr. Geier's work, which never appeared in peer-reviewed medical literature. What defendant did not share with the Court is that The Journal Of American Physicians and Surgeons offered Dr. Geier the opportunity to respond to the anonymous letter attached to defendant's motion. The Journal also noted prominently that the attachment to defendant's motion on which they rely so heavily is a letter "no one has been willing to sign for publication." (*See, Editor's Note to Exh. 19*).

Dr. Geier's reply to the unsigned article published by The Journal Of American Physicians and Surgeons convincingly points out that the unsigned, anonymous internet-letter criticism of his work and reliance on the VAERS database is unfounded.⁷

⁷ VAERS was developed to monitor the safety of vaccines administered in the United States, and was established by an act of Congress. The VAERS database is maintained and operated jointly by both the CDC and the Food and Drug Administration (FDA). The CDC and FDA have published many epidemiologically studies examining the VAERS database to evaluate the safety of vaccines in the United States. The National Immunization Program, Centers for Disease Control and Prevention, has developed a technique for examining the VAERS database. That technique is the same technique that Dr. Geier employed in his epidemiological studies of hepatitis B vaccine, and other vaccines in the VAERS database. The technique involves calculating the incidence rate of reported adverse events to the VAERS database following one vaccine in comparison to the incidence rate of

Moreover, (in addition to not being based on any identifiable individual's opinion, sworn or otherwise) defendant's challenge to Dr. Geier's opinion is without legal basis.

Essentially, defendant argues that unless there is unanimity of opinion among scientists in Dr. Geier's field, free of criticism, Dr. Geier cannot offer his opinion in this case. Unanimity, however, is not the talisman of *Daubert*. In fact, the very reason that the Supreme Court undertook to hear the *Daubert* case was to abolish the earlier *Frye* rule, which required that "the thing from which [an expert's deduction] is made must be sufficiently established to have

reported adverse events to the VAERS database following a second vaccine administered to a similar aged population. The Biologic Surveillance Summaries of the CDC are employed to estimate the number of doses administered, and from this calculate the incidence rate of reported adverse events to the VAERS database following the vaccines under study. Then statistical significance tests are employed, accepting a p-value of < 0.05 as statistically significant, to determine whether there were statistically significant differences in the incidence rates of reported adverse events following the vaccines under study. In addition, the two vaccines under study are compared to determine the relative reporting ratio difference of reported adverse events (i.e. this ratio is a measure of relative risk) in the VAERS database.

The Division of Biostatistics and Epidemiology, Office of Establishment Licensing and Product Surveillance, Center for Biologic Evaluation and Research, U.S. Food and Drug Administration, has epidemiologically evaluated the safety of vaccines in the VAERS using a similar technique to that used by Dr. Geier. Therefore, the technique that Dr. Geier employs to analyze the VAERS database, has not only been developed and published by authors from the National Immunization Program of the CDC, it has also been employed by authors from the FDA to analyze the VAERS database. The CDC has determined that any shortcoming with the technique, such as underreporting, difficulty in determining causal relationship, and lack of precise denominators would apply equally to both vaccines under study. The CDC concluded, "The final comparison in VAERS between the 2 vaccines, while not perfectly precise, should still provide accurate relative qualitative and quantitative relationships."

Dr. Geier's approach to analyzing the VAERS database has been peer-reviewed and found acceptable for publication in numerous well respected peer-reviewed scientific journals including: Experimental Biology & Medicine, Clinical Immunology, Annals of Internal Medicine, Expert Opinion on Drug Safety, Clinical & Experimental Rheumatology, Hepato-Gastroenterology, Annals of Pharmacotherapy, etc. Dr. Geier's work in this regard has been published in more than 20 studies on the safety of vaccines in the peer-reviewed scientific/medical literature. Dr. Geier has also been invited to speak at the Institute of Medicine of the United States' National Academy of Sciences on the safety of vaccines on several occasions, and most recently has been invited to speak at the Institute of Medicine's hearing on autism and vaccines on February 9, 2003. He has also been invited to address the Government Reform Committee of the United States' House of Representatives on the safety of vaccines, and has been accepted as an expert witness on vaccines in Federal Court, State Court, the Vaccine Injury Compensation Program (close to 100 times), and Canadian Court.

gained general acceptance in the particular field in which it belongs.” *Daubert* 509 U.S. at 586-587 (even under *Frye*, general acceptance was the standard, not unanimity). Here, defendant wants to reverse *Daubert*’s criticism of *Frye* (as being too “austere”) and create a more austere standard than even the *Frye* rule (which would allow experts to testify as to only those things on which every person in their field agree).

In sum, the standard defendant asks the Court to apply is simply not the relevant, legal *Daubert* standard. In *Daubert* the Supreme Court held that:

- “of course it would be unreasonable to conclude that the subject of scientific testimony must be ‘known’ to a certainty.” *Id.*, at 590;
- Nothing in the text of this Rule establishes ‘general acceptance’ as an absolute prerequisite to admissibility . . . and a rigid ‘general acceptance’ requirement would be at odds with the ‘liberal thrust’ of the Federal Rules.” *Id.*, at 588.

The anonymous, unpublished criticism defendant points notwithstanding, Dr. Geier’s opinion is based on demonstrably scientifically valid principles. And as highlighted in *Daubert*, defendant’s proper procedure for challenging Dr. Geier’s testimony is cross-examination and the presentation of contrary evidence. As the Supreme Court noted in *Daubert* “vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking” what defendant argues here is shaky testimony. *Id.* at 596. These “conventional devices, rather than wholesale exclusion under an uncompromising ‘general acceptance’ test, are the appropriate safeguards where the basis of scientific testimony meets the standards of Rule 702.” *Id.*

The Court should deny defendant’s motion to exclude the testimony of Dr. Mark Geier.

B. Dr. Byron Hyde.⁸

Dr. Hyde has practiced medicine for 32 years. (*See, CV Exhibit 20*). Since 1984, Dr. Hyde has focused his practice and study on chronic fatigue syndrome ("CFS") and/or myalgic encephalomyelitis. *Id.* Dr. Hyde authored a textbook entitled, The Clinical and Scientific Basis of Myalgic Encephalomyelitis Chronic Fatigue Syndrome. *Id.* He is also a member of the American Association of Chronic Fatigue Syndrome Physicians. *Id.*

Based on his personal examination of Mr. Jeffries and his testing, experience, and observations, it is Dr. Hyde's opinion that the hepatitis B vaccine administered to Mr. Jeffries just prior to the onset of his illness caused him to suffer an autoimmune illness⁹ and chronic fatigue syndrome. (*See, Hyde Reports, Exhibit 21*). Plaintiff's other experts, Drs. Poser, McClellan, and Waisbren agree with this diagnosis.¹⁰

Dr. Hyde bases his conclusion on the following: (i) the proximity of the vaccination to the onset of his illness; (ii) Mr. Jeffries' genetic background or predisposition to autoimmune disease;¹¹ (iii) the fact that Mr. Jeffries was ill at the time of the Vaccine;¹² and (iv) the scientific

⁸ Dr. Hyde, like Dr. Geier and others, testified as an expert on behalf of Mr. Jeffries at the trial conducted in the Court of Federal Claims under the ACT, notwithstanding a *Daubert* challenge raised by trial counsel from the Department of Justice.

⁹ As mentioned above, the hepatitis B expert defendants engaged confirmed that there is a sound scientific basis for the possibility that auto-immune illnesses may result from a hepatitis B vaccination.

¹⁰ Defendant incorrectly argues that "Mr. Jeffries' physicians have been unable to collectively assign a specific diagnosis to his problems."

¹¹ As defendant's expert, Dr. Garb, recognized Mr. Jeffries' elevated HLA-27 condition makes it more likely that he would suffer an adverse reaction to the hepatitis B vaccine. And as Dr. Luggen testified, the fact that Mr. Jeffries' sister and son each have auto-immune illnesses make it more probable that he too would be predisposed to auto-immune illness.

support that the hepatitis B vaccine triggers adverse reactions and symptoms consistent with Mr. Jeffries' symptoms. In his experience, Dr. Hyde has observed these same types of patterns in numerous other patients who have suffered adverse reactions to the hepatitis B vaccine.

Through his practice and research, Dr. Hyde has noted that people with chronic fatigue syndrome almost invariably have an immune dysfunction. Dr. Hyde has assessed Mr. Jeffries' immune system on two occasions and on both occasions found that his immune system was abnormal. Dr. Hyde also concluded that Mr. Jeffries has a "measurable . . . major brain injury" (a Central Nervous System Encephalopathy). According to Dr. Hyde, Mr. Jeffries suffers from "a generalized and severely abnormal immune dysfunction (exhibited through) inflammatory reaction to the arteries of the brain and . . . an inflammatory reaction to the thyroid."

In assessing Mr. Jeffries' SPECT scans, Dr. Hyde noted "changes . . . includ[ing] a vasculitis-like pattern of the Central Nervous System . . . this probably relates to a low-grade inflammatory reaction of the CNS arterial bed." Dr. Hyde further commented that a PET scan of Mr. Jeffries' brain: "showed a wide area of injuries in [Mr. Jeffries'] lower brain . . . [Mr. Jeffries] has really significant changes in that area of the brain . . . There's no way that prior to that immunization he could have done the kind of work that did with this kind of brain. He neither has the strength, the elasticity, the memory."

Without reference to or reliance upon any person's testimony or any identifiable information, defendant challenges the testimony of Drs. Hyde and Waisbren. Defendant argues without expert support that: (i) there is no scientific support for Dr. Hyde's or Dr. Waisbren's

¹² A contraindication for the receipt of a hepatitis B vaccination. (*Exh. 5*).

opinion or methodology; and (ii) their opinions do not satisfy any of the factors enumerated in the *Daubert* case. These arguments are untrue.

The scientific evidence that vaccines, and specifically the hepatitis B vaccine can cause the symptoms from which Mr. Jeffries' suffers is, as detailed above, acknowledged by the vaccine manufacturer, shown in the VAERS database, and not disputed by defendant's experts - all of whom agree that adverse reactions to the hepatitis B vaccine are scientifically valid. The defendant's Motion is devoid of any evidence to the contrary.

While defendant wholly discounts the anecdotal reports of adverse reactions to the hepatitis B vaccine, the Supreme Court clearly determined that the trial court's function "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho* at 152. In arriving at their opinions, Drs. Hyde and Wasibren have applied the same intellectual rigor which characterizes their field of practice. The fact that their field, their professional studies, or their personal experiences require them to rely on voluminous anecdotal reports, does not mean their opinions are unreliable under *Daubert*. In fact, the Supreme Court in *Daubert* stated that:

"in some instances well-grounded but innovative theories will not have been published . . . [accordingly] the fact of publication (or lack thereof) in a peer reviewed journal will be a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised." *Id.* at 593.

Moreover, Dr. Hyde has provided hundreds of papers published in scientific and medical publications concerning adverse reactions to hepatitis B immunization. (*See, Exhibit 22, Bibliography; and Exhibit 23 Papers*).

In sum, Dr. Hyde's opinion is based on the universally accepted and scientifically valid proposition that vaccines can cause adverse reactions and symptoms of the type plaguing Mr. Jeffries. His opinion is further based on reproducible clinical and scientific evidence supported by a multitude of medical experts and peer-reviewed communications.

C. Dr. Burton Waisbren.

Like Dr. Hyde, Dr. Waisbren is a mature physician with extraordinary experience in treating patients who suffer adverse reactions to vaccines. (*See, CV and report attached as Exhibit 24*). Even defendant's physician, Dr. Garb, recognizes that Dr. Waisbren is one of the preeminent experts with experience in treating persons and studying adverse reactions to vaccines. (*Exh. 6*).

In his report at page 11, Dr. Waisbren identifies many peer-reviewed articles that suggest overwhelmingly the scientific validity that hepatitis B vaccination causes adverse reactions in recipients. These reactions are primarily of the autoimmune variety, the essence of Mr. Jeffries symptoms and illness.

For all of the above reasons, Dr. Waisbren too should be permitted to offer his opinions which are premised on scientifically valid principles, in accordance with *Daubert*.

VI. Other Of Plaintiff's Experts (Who's Opinions Defendant Does Not Challenge) Also Opine That The Hepatitis B Vaccine Caused Mr. Jeffries' Undisputed Illness.

A. Dr. Charles Poser.

It is Dr. Poser's opinion that the hepatitis b vaccine caused Mr. Jeffries disability. His opinion, however, is not challenged by defendants.

Dr. Poser graduated from medical school in 1951 and has been practicing medicine for 52 years. (*See, Exhibit 25*). Since 1981, Dr. Poser has been a professor of neurology at the Boston University School of Medicine, a lecturer in neurology at Tufts, and since 1996, Dr. Poser has served as a visiting professor of neurology at Harvard Medical School where he is currently working. *Id.*

Dr. Poser has published approximately 240 articles in scientific journals, a number of abstracts, 85 chapters in reviews, and five books. *Id.* Dr. Poser has also served as editor for 4 additional books. *Id.* Dr. Poser developed the diagnostic criteria for multiple sclerosis which became widely recognized as the accepted criteria that everyone used for that illness. Dr. Poser's MS criteria were published in 1983 and are still in use, being published on essentially a daily basis.

Dr. Poser has seen a number of patients with chronic fatigue syndrome and authored a paper in 1995 entitled "Myalgic Encephalomyelitis / Chronic Fatigue Syndrome and Multiple Sclerosis: Differential Diagnosis?" Dr. Poser has analyzed the phenomenon of adverse reactions to vaccines since the 1950s. In 1987, Dr. Poser wrote a paper entitled "Neurologic Syndromes That Arise Unpredictably" which discusses the complications of vaccinations. And Dr. Poser has written 40 to 50 papers about neurological complications of vaccinations.

Dr. Poser personally examined Mr. Jeffries in addition to reviewing his medical records. Dr. Poser explained that Mr. Jeffries' illness is one that most commonly results from vaccinations and infections. And Dr. Poser testified that he believes that CFS is a common form of the illness, "a common complication of vaccinations." Dr. Poser testified that all vaccines are capable of producing injury to both the central and peripheral nervous systems. He mentions

that there is “enormous literature of cases and theories” studying the variety of vaccine-related neurologic complications. Dr. Poser also testified that the phenomenon has been produced experimentally in animals, known as “experimental allergic neuritis” and “experimental allergic encephalomyelitis.”

Dr. Poser pointed out that the literature clearly shows that individuals respond in a very individual manner to any vaccine, and the responses can vary from central nervous system disorders, peripheral nervous system disorders, or combinations of the two. The differences in reactions can be both because of genetic differences in the individual as well as “immunological baggage” based on their individual prior exposures.

According to Dr. Poser, it is not only biologically plausible that the vaccine caused Eric’s injury, but that there is evidence in the medical literature to support this biological plausibility. Dr. Poser testified that there exists a number of well-documented reports of neurological complications following hepatitis B vaccine, ranging from optic neuritis to transmitting myelitis. And this is one of the bases for Dr. Poser’s conclusion, to a reasonable degree of medical certainty, that Mr. Jeffries’ illness was caused by the hepatitis B vaccine he received.

Dr. Poser reviewed results of Mr. Jeffries’ SPECT scan. According to Dr. Poser, the SPECT scan “revealed a pattern consistent with changes seen in chronic fatigue syndrome, a marked increase of antimicrosomal antibodies, an increase of CD4/CD8 cell ratio, and a thyroid biopsy showing papillary carcinoma.” Dr. Poser stated that it was his opinion that:

“Mr. Jeffries gives . . . the classical history of chronic fatigue syndrome (CFS) . . . the temporal relationship . . . [of the illness] to the vaccination . . . is such as to strongly suggest a causal relationship . . . I have seen several cases of classical CFS immediately following, and almost certainly resulting, from [a hepatitis B]

vaccination [and] I am impressed by the results of the SPECT and PET scans and by the changes in [Mr. Jeffries'] immune system." *Id.*

According to Dr. Poser, it is not only biologically plausible that the vaccine caused Mr. Jeffries' injury, but that there is evidence in the medical literature to support this biological plausibility.

B. Dr. Michael McClellan.

Like Dr. Poser, Mr. Jeffries' primary care physician since 1998, Dr. Michael McClellan, opines that the vaccine caused Eric's illness, but his opinion is not challenged.¹³

Dr. Michael McClellan is an internist who has followed Mr. Jeffries' care for many years. Dr. McClellan graduated from the University of Cincinnati Medical School. (*See Exhibit 26*). He completed his residency in internal medicine at The Christ Hospital. *Id.* Dr. McClellan is Board certified in internal medicine, and has been in private practice since 1991. *Id.*

Dr. McClellan has eliminated all conceivable causes for Eric's illness, but for the vaccine and testified that there are well-published documented case reports of people having very similar reactions as Mr. Jeffries to the hepatitis vaccine.

Conclusion

The reasoning and methodology underlying the testimony of Drs. Hyde, Geier, and Waisbren is scientifically valid and is properly applied to the facts in issue. Their testimony will "assist the trier of fact to understand the evidence or to determine a fact in issue," namely the cause of Mr. Jeffries' undisputed disability. For the above reasons, the Court should deny defendant's prayer and allow Drs. Hyde, Waisbren, and Geier to offer their opinions at trial.

¹³ And Mr. Jeffries' primary care physician who preceded Dr. McClellan, Dr. Donald Nunlist-Young, does not disagree. (*See Exhibit 27*).

Respectfully submitted,

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CERTIFICATE OF SERVICE

The foregoing was delivered, via regular U.S. Mail William R. Ellis, Esq., Wood & Lamping LLP, 600 Vine Street, Suite 2500, Cincinnati, Ohio 45202, this 14th day of January, 2004.

/s Michael A. Roberts

Index Of Exhibits

1. Hepatitis B Vaccine Manufacturer Insert
2. Dr. Robert Curran Report
3. Dr. Newton Bullard, Deposition Excerpts
4. Jeff Champagne, Deposition Excerpts
5. Lucinda Palmer, R.N., Deposition Excerpts
6. Report of Dr. James Garb
7. Lloyd, et al, "What is Myalgic Encephalomyelitis?" *The Lancet* June 4, 1998
8. Gherardi, et al. study
9. Authier, et al. study
10. Gherardi, et al. study
11. Authier, et al. article
12. Christopher P. Howson et al., *Institute of Medicine*, Adverse Effects of Pertussis and Rubella Vaccines, 48, 53 (1991)
13. Kathleen R. Stratton et al., *Institute of Medicine*, Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, 21 (1994)
14. Hassan & Oldman, *British Medical Journal*, Reiter's Syndrome and reactive arthritis in health care workers after vaccination, 1994: 309;94-5
15. Case study of Maillefort et al.
16. Institute Of Medicine - 1994 report
17. Curriculum Vitae of Dr. Mark Geier
18. Report Of Mark Geier Concerning Mr. Jeffries (*filed manually, due to volume*)
19. Reply of Dr. Geier, *The Journal Of American Physicians and Surgeons*
20. Dr. Byron Hyde Curriculum Vitae
21. Dr. Byron Hyde Reports Concerning Eric Jeffries
22. Bibliography of Studies, Reports, Articles on adverse reactions to vaccines
23. Studies, Reports, Articles on adverse reactions to vaccines (*filed manually, due to volume*)
24. Dr. Burton Waisbren, Curriculum Vitae and Report Concerning Mr. Jeffries
25. Dr. Charles Poser, Curriculum Vitae and Report Concerning Mr. Jeffries
26. Dr. Michael McClellan, Curriculum Vitae and Report Concerning Mr. Jeffries
27. Affidavit of Dr. Donald Nunlist-Young